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<b>(21) International Application Number:</b> PCT/FI98/00503 <b>(22) International Filing Date:</b> 11 June 1998 (11.06.98) <b>(30) Priority Data:</b> 972532 13 June 1997 (13.06.97) FI <b>(71) Applicant (for all designated States except US):</b> CULTOR CORPORATION [FI/FI]; Kyllikinportti 2, FIN-00240 Helsinki (FI). <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> HAARASILTA, Sampsa [FI/FI]; Louhentie 9 B, FIN-04230 Kerava (FI). REINIKAINEN, Tapani [FI/FI]; Pajalahdentie 21 A 16, FIN-00200 Helsinki (FI). SULANTO, Seija [FI/FI]; Verkkotie 30 H 16, FIN-00980 Helsinki (FI). <b>(74) Agent:</b> KOLSTER OY AB; Iso Roobertinkatu 23, P.O. Box 148, FIN-00121 Helsinki (FI).		<b>(81) Designated States:</b> AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>With amended claims and statement.</i> <i>In English translation (filed in Finnish).</i>
<b>(54) Title:</b> PRODUCT, METHOD FOR ITS MANUFACTURE, AND ITS USE  <b>(57) Abstract</b>  The invention relates to a premix useful in food industry, the premix containing a pulverized plant sterol and a conventional foodstuff raw material. The invention further relates to methods for the manufacture of the premix, to the use of the premix as such and in the manufacture of foodstuffs, and to edible products containing the premix. Bakery products containing the premix of the invention are described in particular.		

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**PRODUCT, METHOD FOR ITS MANUFACTURE, AND ITS USE****FIELD OF THE INVENTION**

The invention relates to a premix useful in food industry, the premix containing a pulverized plant sterol and a conventional foodstuff ingredient  
5 which is cereal, leguminous plant, milk powder or the like, such as fruit, vegetable and/or berry, particularly in a powder form, bone, feather, fish, meat or rind. The invention further relates to methods for preparing the premix, to the use of the premix as such and in the manufacture of foodstuffs, and to edible products containing the premix. In particular, bakery products containing the  
10 premix in accordance with the invention are described.

**BACKGROUND**

The cholesterol-lowering effect of plant sterols has been known since the 1950's, and the literature of the field therefore includes several reports concerning the positive effects of plant sterols on the cholesterol level.  
15 New reports include, for example, the research by Heinemann et al., Eur. J. Clin. Pharmacol. 40 (Suppl. 1), 1991, 59-63, about the effect of sitostanol and sitosterol on the absorption of cholesterol in the intestine by using an intestinal perfusion technique. Sitostanol was found to reduce the cholesterol absorption by as much as 85% and sitosterol by 50%.

20 Nevertheless, the use of plant sterols has not been very extensive, due to for example their poor availability and therefore high price. One of the greatest problems has been the poor solubility of plant sterols, since they are not soluble in water and are also poorly soluble in fats. The manufacture of edible products containing plant sterols is thus technically difficult, and the final  
25 products are not satisfactory as regards structure and taste characteristics.

Attempts have been made to solve the solubility problem by producing fat-soluble forms, such as fatty acid esters, from the plant sterols by dissolving or emulsifying the plant sterols or said derivatives in a fat or a fat component and by using them particularly in connection with the use of fats.  
30 Methods for preparing fat-soluble plant sterol esters are disclosed, for example, in EP 195 311 (Yoshikawa Oil & Fat Co., Ltd.), DE 2,035,069 (Procter & Gamble Co.) and WO 92/19640 (Raisio Margariini Oy). Solubilized sterol compositions are disclosed, for example, in EP 289 636 (Asahi Denka Kogyo Kabushiki Kaisha) and in U.S. Patent 5,244,887 (Straub). However, the use of  
35 fat is not nutritionally recommendable, especially when the objective is to lower

the blood cholesterol level and to avoid excessive energy intake.

So there is an obvious demand for providing the consumer with agreeable plant sterol products which do not require the use of fat. Hence, there is a particular demand for such products that are applicable to everyday  
5 use and preferably familiar to the consumers, and also otherwise, are a part of a normal diet. These products comprise, for example, products containing cereal, ready-prepared foods and processed meat products. Bread and other bakery products can be mentioned as a special field.

The literature of the field describes the plant sterol added as such to  
10 bakery products. The Soviet patent 414 989 discloses a method for manufacturing dietetic baked products containing  $\beta$ -sitosterol. In accordance with the method,  $\beta$ -sitosterol, that is premixed with vegetable oil, is mixed with the other dough ingredients, whereby the flour is added last, and the obtained dough is moulded and baked in the oven. The amount of  $\beta$ -sitosterol is preferably at  
15 least 5% by weight of the final product. According to the reference, the products are suitable for persons having disturbances in lipid metabolism, but the characteristics of the products are not described in greater detail, and their effects are not disclosed either. Neither does the reference mention processing problems due to the poor solubility of  $\beta$ -sitosterol, and thus no solution is  
20 disclosed for these problems. In particular, it can be noted that even at temperatures exceeding 80° C sitosterol dissolves very slowly in fat and solidifies quickly. Baking is thus technically difficult. Moreover, the use of hot oil in a bakery is problematic because of the oxidation risk and effects on native gluten and living yeast.

25 The Japanese Patent application Hei 2-299548 discloses a baked cholesterol-lowering product containing  $\beta$ -sitosterol and a method for its manufacture. According to the reference, the baked products may be, for example, biscuits, cookies or the like, and they are prepared by adding  $\beta$ -sitosterol, that is premixed with wheat flour and/or egg white, to the other  
30 dough ingredients, by mixing and processing the dough in a conventional manner. The baked product preferably contains  $\beta$ -sitosterol 1 to 30% by weight, according to the reference, an amount exceeding that brings about a strange mouth-feel. According to the reference, a smoother dough whose processing properties improve is obtained in this manner by adding the  $\beta$ -  
35 sitosterol to the flour and/or egg white. However, the tests conducted in connection with the present invention show clearly that commercially available si-

tosterol and sitostanol preparations do not mix well enough manually with wheat or rye flour, but they tend to cake causing, for example, processing problems and white lumps in the crumb and crust of bakery products.

Practice has thus shown that the prior art methods are not sufficient  
5 to solve the processing problems. When  $\beta$ -sitosterol is used as such, even though premixed with fat, flour or some other suitable component, it is impossible to produce a homogenous and smooth dough. Lumps appearing in the dough hamper the normal use of the devices at the dough forming and processing steps, such as a moulding step, and at the proofing step the rise remains weaker than usual. As a consequence, the final products obtained are  
10 flat and deformed bakery products, which the consumer finds unpleasant and strange by structure, appearance and mouth-feel. It is to be mentioned that sitosterols and sitostanols as such have no adverse effect on the taste or mouth-feel of the products. The problems are the poor solubility of the compounds, particularly insolubility in water, and caking during the use.  
15

#### DESCRIPTION OF THE INVENTION

The object of the present invention is to provide such a plant sterol product that can be used as an edible product as such or in the manufacture of other edible products without that is causes processing problems or strange  
20 taste or structure characteristics in the final product.

The object of the present invention is also to provide such edible products that have a cholesterol-lowering effect thanks to the plant sterol they contain, but whose other characteristics are familiar and agreeable to the consumer.

25 In accordance with the present invention, these objects are achieved by forming a premix that contains a pulverized plant sterol and a conventional foodstuff raw material that is selected from a group comprising cereal, leguminous plants, milk powder and/or fruit, vegetables and berries, particularly in a powder form, and bone, feather, fish, meat and/or rind, and by  
30 using this premix as such or in the manufacture of edible products, instead of an untreated plant sterol or a plant sterol derivative modified in its solubility characteristics.

Thus the invention relates to a premix containing a pulverized plant sterol and a conventional foodstuff raw material which is cereal, leguminous  
35 plant, milk powder and/or fruit, vegetable or berry, particularly in a powder form, bone, feather, fish, meat and/or rind.

The invention also relates to methods for manufacturing the premix.

The invention further relates to the use of the premix as an edible product as such, as an additive in other edible products, or in the manufacture of other edible products.

5           The invention particularly relates to the use of the premix in the manufacture of bakery products.

The invention also relates to bakery products containing the premix in accordance with the invention.

10           Further, the invention relates to the use of a plant sterol in bakery products as an anti-staling agent.

So the premix in accordance with the present invention comprises two main components, a pulverized plant sterol and a conventional foodstuff raw material which is cereal, leguminous plant, milk powder, fruit, vegetable and/or berry, bone, feather, fish, meat or rind.

15           The plant sterol may be any phytosterol having a cholesterol-lowering effect. The plant sterol is preferably  $\beta$ -sitosterol, i.e. 24-ethyl-5-cholesten-3 $\beta$ -ol, or especially its hydrogenated form  $\beta$ -sitostanol, i.e. 24-ethyl-5 $\alpha$ -cholestan-3 $\beta$ -ol. Other suitable plant sterols include for example brassicasterol, campestenol and clionastanol. Commercially available plant sterols  
20 are often mixtures of plant sterols that are also appropriate for use according to the present invention.

The other main ingredient of the premix is preferably cereal or the like. In the present invention, this term refers to, for instance, ordinary cereals, such as wheat, rye, barley, oat, buckwheat, millet, and maize, rice and potato  
25 starch. Leguminous plants include, for instance, soybean, pea and other beans. Cereals and leguminous plants can be used in a form of various flours or flour products. Concerning wheat, for instance, wheat bran, coarsely ground wholemeal wheat, wheat germs, grit, and flours of various degrees of grinding, such as wholemeal flour, yeast bread flour, coarse wheat flour, kernel wheat  
30 flour, and so on, can be used, and concerning rye, for instance, wholemeal rye flour, sifted rye flour, bolted rye flour, coarsely ground wholemeal rye, and so on, can be used. Instead of flour, also seeds or grains can preferably be used as such or pretreated in a suitable manner, like for instance, husked, polished or pre-crushed. The premix may also contain milk powder as the other main  
35 ingredient, the milk powder being a widely used bulking agent in food industry,

or berry, vegetable or fruit, especially in a powder form, or, particularly as a raw material of animal feed industry, bone, feather and rind, meat or fish.

The premix is preferably a mixture forming a suspension, preferably containing, in addition to the plant sterol, as the second main ingredient a suspension forming substance slowly soluble or insoluble in water, such as ground cereal, leguminous plant or milk powder. A homogenous premix is thus obtained, in which plant sterol particles are evenly distributed among flour particles or even adsorbed onto their surface. Due to its poor solubility, the premix does not dissolve, even during the use, causing separation of insoluble plant sterol, but the mixture remains constantly homogenous and it is easy to form an even suspension, when necessary.

In addition to the above-mentioned ingredients, the premix may also contain salt and other minor components, such as vitamins, trace elements, seasonings, emulsifying, stabilizing and thickening agents, enzymes, etc. However, their proportion is so insignificant that it is not feasible to add the plant sterol to the premix by means of them.

The premix may also contain water, however, the state is generally solid or semi-solid, for instance, such that can be extruded, pumped, spooned out or even drunk.

The amounts of the plant sterol and the second main ingredient in the premix may vary greatly according to the composition and use of the premix. Generally, the amount of the plant sterol is about 1 to 60% by weight, preferably about 5 to 50%, more preferably about 10 to 40%, and most preferably about 10 to 20% by weight.

A preferred premix is a mixture containing a plant sterol and flour. The flour is preferably rye, buckwheat, maize or wheat flour, and the premix contains about 5 to 25%, most preferably about 10 to 20%, of plant sterol. In the most preferred form the premix does not contain any other components. However, the premix may contain a varying amount of water, and for instance, thickening agent.

The premix may be a so called premix, to which considerable amounts of other substances are added in connection with the use, or a so called complete mix, that is not supplemented with other substances in connection with the use, possibly apart from water or other liquid.

The method in accordance with the invention for preparing a premix is characterized in that a homogenous, pulverized mixture is formed from a

plant sterol and a conventional foodstuff raw material, which is cereal, leguminous plant, milk powder or the like, such as berry, vegetable or fruit, especially in the form of powder, bone, feather, fish, meat or rind.

In accordance with the present invention, the premix is preferably  
5 prepared by grinding the plant sterol and the second main ingredient together to form a pulverized mixture. Grinding can be carried out by using any process by which sufficiently finely divided and homogenous premix is obtained, in order that the above-mentioned problems can be avoided. Hence, applicable processes comprise, for example, methods based on kinetic energy, methods  
10 based on quick impact-mixing, methods based on the use of friction, etc. Methods and devices applicable to grinding are disclosed, for instance, in patent applications FI 963904 and FI 932853.

In the present invention, an advantageous method is to grind a  
plant sterol and cereal, a cereal mixture or the like together with a grinder op-  
15 erating on a so called impact milling principle. For instance, Atrex mill of Megatrex Oy represents this kind of a device. The structure of the device is shown as a schematic view in Figure 1, the operating principle of the rotors is illustrated in Figure 2. A device of this type can be used both for forming a very finely divided mixture, whereby the plant sterol is generally ground as such or  
20 together with flour, milk powder or fruit, berry or vegetable powder, bone, feather, meat, fish or rind, and for forming a mixture of greater particle size, whereby even grains of cereal and seeds of leguminous plants as such or pretreated in a suitable manner can be used. A particularly advantageous method for grinding the plant sterol and the cereal or the like is an impact  
25 milling method, in which the plant sterol and the grains of cereal, in the form of whole grains, husked grains, pre-crushed grains or husked, pre-crushed grains, are homogenized and pulverized together by a quick impact-mixing treatment using an Atrex mill or mixer or a similar device. In the present invention, it was found that a completely homogenous mixture was obtained in this  
30 way, the particle size being a less important parameter. Even though the inventors do not wish to commit themselves to any particular theory, they believe that the plant sterol is here adsorbed onto the surface of grains, thus facilitating the formation of a homogenous mixture. This method is well suited for preparing a cereal-based premix containing plant sterol, the premix containing  
35 in a preferred form only plant sterol and rye, buckwheat, maize or wheat flour. The premix grinding can be controlled by attaching a sifting and/or classifying



device to the grinding device. So if necessary, coarse fractions can be re-supplied to the impact milling device for further grinding. Grinding can be carried out both as dry grinding and wet grinding, whereby the temperature and moisture control is effected by adjusting the power of the impact milling device  
5 and/or the amount of liquid in the device. In the present invention, dry grinding is considered advantageous. The moisture content of cereal does not place restrictions on processing, but in practice it is easy to use storage moist cereal. When a mixture of storage moist cereal and a plant sterol is pulverized with a device based on quick impact-mixing, without additional liquid or with the low-  
10 est possible amount of liquid, using a high homogenizing power, the temperature of the grains rises due to the effect of mechanical energy on the grains, whereby a heat treatment of the grains is provided in conjunction with grinding, which increases the falling number of the grains, and as a consequence the baking characteristics of the cereal improve. Thus the falling number of cereal  
15 does not place any restrictions either, so cereal having a lower falling number can also be used in the implementations in accordance with the invention.

The pulverization in accordance with the invention can also be carried out, for example, with an air jet mill wherein the particles that have been fluidized into a carrier gas, typically air, and that are to be pulverized, are con-  
20 ducted to collide at a high speed. This pulverizer preferably also comprises a classifier where the pulverized material is classified into fractions having different particle sizes. The dry grinding, as also the wet grinding, can also be carried out in mills based on the use of friction, for example in a ball mill.

The parameters used in the grinding in each particular case are  
25 determined according to the structure of the grinding device used and the substance or mixture to be pulverized.

The premix of the invention can also be prepared by mixing the separately pulverized ingredients carefully together into a homogenous mixture. A pulverized plant sterol can be formed in various ways for this purpose.  
30 A pulverized plant sterol can thus be obtained by sifting, for instance, a commercially available plant sterol product. Sifting is carried out by using conventional methods and sifters. For instance, a widely used sifting device in baking by Bühler-Miag, Milan, Italy, with mesh sizes of 1600  $\mu\text{m}$ , 1000  $\mu\text{m}$ , 670  $\mu\text{m}$ , 390  $\mu\text{m}$ , 275  $\mu\text{m}$  and 132  $\mu\text{m}$  is excellently suited for this purpose. Another  
35 way to prepare pulverized plant sterol is to grind the plant sterol as such, for instance, with a mill based on impact milling principle, with a mill based on ki-

netic energy, with a mill based on friction or with a mill based on collision energy.

Also in this case, the pulverization can be carried out on a crystalline plant sterol as such or on a mixture of a plant sterol and a second component, such as an appropriate admixture. Appropriate admixtures for the present invention comprise, for example, various sweetening agents and other structure and/or flavour enhancers. Methods that are particularly suitable for this purpose are disclosed in Finnish patent application 963904.

The above-described methods can be used to form a homogenous premix from a pulverized plant sterol and the second main ingredient of the premix, i.e. cereal, leguminous plant, milk powder or the like, such as berry, fruit and vegetable, especially in a powder form, bone, feather, fish, meat or rind, and other possible ingredients. When using a pulverized plant sterol, the pulverization is less important than the certainty of homogenization. Hence, also other methods, that are partly insufficient for pulverization, are well suited for preparing a premix like this. If both ingredients are in a pulverized form, mills, homogenizing devices and grinding devices used in food industry are applicable to form a premix. Particularly devices used in meat processing and baking industries have proved to be useful in the present invention. By way of example, blenders, such as devices of Lödige type, can be mentioned.

The sufficient degree of pulverization and homogeneity of the premix, and the plant sterol contained therein, is determined in accordance with each implementation. In granular products, such as animal feed, a premix, whose degree of grinding is not as high as that of a plant sterol used in delicate bakery products made from wheat, can thus be used in general. The manufacturing process is also of significance. Thus, it has been found that if the plant sterol is pulverized as such to be mixed, for instance, with flour, the particle size is generally to be small, less than about 200  $\mu\text{m}$ , most preferably less than 132  $\mu\text{m}$ , preferably about 60 to 70  $\mu\text{m}$ , in order that the outcome is good. On the other hand, when the plant sterol is ground, in accordance with a preferred method of the invention, together with grains of cereal, the particle size of mixture components is not so significant, but a homogenous mixture is obtained even with a mean particle size of about 500  $\mu\text{m}$ . Consequently, the particle size of a product used in accordance with the present invention varies considerably. Figure 3 shows the results of a particle-size analysis of the premix formed by the above-mentioned preferred method. The analysis was car-

ried out by sifting a 10% sitostanol-rye-flour mixture with the above-mentioned Bühler-Miag sifting device for 5 minutes using sifters of 1600  $\mu\text{m}$ , 1000  $\mu\text{m}$ , 670  $\mu\text{m}$ , 275  $\mu\text{m}$  and 132  $\mu\text{m}$ . The results of a particle-size analysis (PAMAS) of sitostanol ground once with an Atrex grinder are shown in Figure 4, respectively.

The premix of the invention is widely applicable for use. The premix can be used as an edible product as such, as an additive in edible products or as an ingredient in the manufacture of other edible products. Due to its structure, plant sterol content and high fibre content, it is particularly well suited for consumption, in the same fashion like muesli, bran or cereals, as accompaniment to, for instance, curdled milk, yoghurt, sour milk and other milk products, thickened dessert soups, berry soups and the like. In households, it can also be used for making porridges, gruels and high-fibre drinks and snacks. It is applicable to the same uses also in food industry where a product of the type of a so called instant porridge or gruel, a high-fibre milk product or a drink containing cereal, etc, can be produced therefrom, in addition to which it can naturally be sold in a form of conventional baking flour, pizza making flour or a porridge mix. The premix is also an extremely good ingredient in meat processing industry for the manufacture of various types of sausages and meat mixes, and in processed and ready-to-eat food industries where suitable applications abound from pea soup to liver-rice casserole and macaroni-meat casserole. One particular use is also fibre-containing sweets, such as liquorice. It is to be noted, that in the present invention, the terms food product and food industry also comprise animal feeds and fodders and the manufacture thereof. The premix is also naturally applicable to use in animal feeds, compressed and dry pet foods, and processed and ready-to-eat foods. A preferred implementation of the present invention is the manufacture of bakery products.

In accordance with the present invention, a preferred final product is a bakery product containing the premix of the invention.

The bakery product in accordance with the invention may be a soft bakery product, such as a bread (wheat bread, rye bread, yeast bread, etc), a sweet baked product (coffee bread, cake, pastry, etc) or a dry bakery product, such as a crispbread, a digestive biscuit, other sweet or salted biscuit, a rusk, a thin crispbread, a cracker, a baked snack, a wafer, an after-heat bread or the like.

Bakery products are prepared following the conventional methods and recipes of the field, but a pulverized plant sterol is added as a premix or a semi-finished product or as such. The most advantageous method is to form the premix in connection with baking, i.e. to add then the pulverized plant sterol as such to the flour, or to use premixes or semi-finished products, which are also mixed first with the flour, whereafter the dough is prepared in a conventional manner.

The bakery product of the invention thus comprises a premix containing pulverized plant sterol and cereal, leguminous plant, milk powder, fruit, berry and/or vegetable, especially in powder form, and conventional ingredients of bakery products. The bakery product contains a sufficient amount of plant sterol for achieving a desired effect. A useful amount is about 0.3 to 5.0%, preferably about 0.5 to 3.0% and most preferably about 1 to 2% of plant sterol. Hence for instance, a bread serving of about 100 to 150 g (2 to 4 slices) provides a sufficient amount of plant sterol for achieving the desired physiological effect, i.e. a lowering effect on blood cholesterol level. It is to be mentioned, that excessive plant sterol contents, for instance a content of 6 to 10%, may have an adverse effect on the appearance of the bakery product, causing unpleasant gray shine on the surface of the product. However, it is obvious that the values given, like all other numerical values given herein, are only trend-setting. In accordance with the invention, any amount that is sufficient for achieving the desired effect and that has no adverse effect on the structure or taste characteristics of the final product can thus be used.

The invention further relates to the use of the premix or the product, particularly a bakery product, containing premix, as a cholesterol-lowering substance.

In the present invention, the plant sterol is found to have an improving effect on the structure and taste of bakery products as well as on their shelf life. Thus the invention also relates to the use of the plant sterol in bakery products as an agent improving structure and shelf life. For this purpose, equivalent amounts of plant sterol is added to a bakery product as described above.

The invention is described in greater detail by means of the following examples. These examples are only provided to illustrate the invention, and they should not be considered to restrict the scope of the invention in any way.

**Example 1****a) Preparation of a pulverized plant sterol by jet-pulverizing**

4 kg of sitostanol (Kaukas Oy) was jet-pulverized with a dry collision grinder using a classifier (Oy Finnpulva Ab), grinder FP3). The carrier gas was  
5 air having a temperature of about 60°C and a feed pressure of 2 to 3 bar.

**b) Preparation of a pulverized plant sterol by impact-milling**

6 kg of  $\beta$ -sitosterol was pulverized with a grinder based on the impact milling principle (Atrex mill, Megatrex Oy, Harjavalta) .

10 Processing conditions were as follows:

Upper rotor (rpm)	3000
Lower rotor (rpm)	3000
Mass flow (kg/min)	1
Temperature (°C)	25

15

When passing through the grinder, the plant sterol particles are ground into a pulverized mixture whose volumetric mean particle size is about 21  $\mu$ m. PAMAS analysis of the particle size distribution of the mixture is shown in Figure 4.

20

**Example 2****Preparation of a homogenous plant-sterol-flour mixture suitable for baking**

2 kg of pulverized plant sterol ( $\beta$ -sitosterol or  $\beta$ -sitostanol, Kaukas Oy) was carefully mixed in a tub with 18 kg of grains of cereal. The grains may  
25 be grains of rye or grains of wheat husked in various ways. The mixture was ground with a grinder based on the impact milling principle, the grinder represented by the Atrex mill (Megatrex Oy, Harjavalta). Figure 1 shows a schematic view of the structure of an Atrex mill. Figure 2 illustrates the principle of the rotors.

30

Processing conditions were as follows:

Upper rotor (rpm)	3000
Lower rotor (rpm)	3000
Mass flow of grains (kg/min)	2.5
35 Temperature of rye (°C)	25

When passing through the grinder, the grains are crushed and the plant sterol particles are ground with the grains into a homogenous plant sterol-flour mixture.

### Example 3

#### 5 Preparation of a homogenous plant-sterol-flour mixture suitable for baking

0.5 kg of pulverized plant sterol (prepared according to example 1) having a particle size of less than 132  $\mu\text{m}$  was mixed with 4.5 kg of rye flour with a Lödige mixer (Gebrüder Lödige Maschinenbau GmbH, Paderborn, Germany). The mixing time was 15 min.

With the method a homogenous plant-sterol-flour mixture suitable for baking can also be produced with wheat flour, yeast bread flour or whole-meal flour.

### Example 4

#### 15 Preparation of a pulverized plant-sterol-sugar mixture

20 kg of sitosterol (Kaukas Oy) was added as such to 180 kg of saccharose and the mixture was jet-pulverized with a dry collision grinder using a classifier (Oy Finnpulva Ab, grinder FP3P, classifier FPC15R). The carrier gas was air having a temperature of 63°C and a feed pressure of 2.4 bar.

### 20 Example 5

#### Preparation of a rye bread containing plant sterol

A rye bread was prepared in a conventional manner, but part of the rye flour was replaced with a flour mixture containing 10% sitostanol, to the effect that the plant sterol content of the dough was 1.5%. The plant-sterol-flour mixture was prepared according to example 2.

The bread composition was as follows:

	Sourdough	500 g
	Rye flour (coarse)	150 g
30	10% plant-sterol-rye-flour mixture	150 g
	Water (37°C)	100 g
	Yeast bread flour	100 g
	Salt	15 g
	Yeast (compressed)	15 g

The dough was mixed with a Hobart mixer (Hobart Canada, North York, Ontario, Canada) for 1 minute at speed 1 and thereafter for 4 min at speed 2. The lay time of dough was 60 min. The dough was scaled into a bar and put into a dough mould. The proofing time was 40 min and humidity 70 to 75%. The bread was baked in the oven for 35 to 40 min at a temperature of 230 to 240°C.

A reference bread containing no plant sterol was prepared according to the same recipe. The bread containing plant sterol was slightly lighter in colour, the structure (porosity, pore size, crumbliness, smoothness), mouthfeel, aroma and taste corresponded to those of the reference bread. The results of the analysis showed that the plant sterol added as a flour premix distributes evenly in bread, and does not dissolve or oxidize during the baking process used.

#### Example 6

##### Preparation of a rye bread containing plant sterol

A rye bread was prepared in the manner described in example 5, but using a flour mixture containing 20% sitosterol prepared according to example 3.

A reference bread was a rye bread prepared according to the same recipe but without the sitosterol addition. No differences were found in the structure or stiffness of the doughs in this test, nor were there differences in the taste of the breads. However, the bread containing plant sterol was slightly lighter in colour than the reference bread.

#### Example 7

##### Preparation of a rye bread containing plant sterol

A pulverized sitosterol having a particle size of less than 132 µm and prepared according to example 1 was manually mixed with the flour before other ingredients were added. Mixing was carried out very carefully and lumps forming in the flour mixture were broken. The dough contained plant sterol 1.3% by weight.

#### Bread composition:

	Sourdough of crushed cereal	500 g
	Rye flour	287 g
	Pulverized plant sterol	13 g
35	Water (37°)	100 g
	Yeast bread flour	100 g

Salt	15 g
Yeast (compressed)	15 g

Baking conditions were the same as in example 5. The bread containing plant sterol was slightly lighter. The structure of bread (porosity, pore size, crumbliness, smoothness), mouth-feel, aroma and taste corresponded to those of the reference bread.

#### Example 8

##### Preparation of a rye bread containing plant sterol

The test baking described in example 7 was repeated using a sifted sitostanol with a particle size of less than 132  $\mu\text{m}$  instead of the pulverized sitosterol. Also this test produced a bread having a slightly lighter colour and corresponding in structure and taste to the reference bread.

#### Example 9

##### Preparation of a wheat bread containing plant sterol

Part of the flour was replaced with a premix containing 10% sitostanol. The premix was prepared according to example 2 by grinding plant sterol together with husked grains of wheat (ash content 1.78). The degree of husking corresponds to dark wheat grit. The plant sterol content was 1.5% by the dough weight.

Bread composition was as follows:

Wheat flour	454 g
10% plant-sterol-wheat-flour mixture	150 g
Sugar	8 g
Rape-seed oil	13 g
Water	350 g
Bread improver (Supergamma, Zeelandia)	9 g

The ingredients were mixed with a Hobart mixer for 1 minute at speed 1, and thereafter for 4 min at speed 2. The dough lay time was 10 min. The proofing time was 40 min and humidity 70 to 75%. The breads were baked in the oven for 17 min at a temperature of 210°C.

A reference bread containing no plant sterol was prepared according to the same recipe. The appearance, aroma, taste and structure (porosity, pore size, smoothness) of the bread containing plant sterol corresponded to



those of the reference bread. The bread containing plant sterol had a moister mouth-feel and it kept fresh for 5 days.

#### **Example 10**

##### **Preparation of buns containing plant sterol**

5 A plant sterol was added to a dough by replacing part of the sugar with a sugar-sitosterol premix jet-pulverized according to example 4, the mixture being mixed with the wheat flour before liquid and fat were added. The plant sterol content of the dough was 2%.

10 Composition of buns was as follows:

	Wheat flour, semi-coarse	210 g
	Wheat flour, coarse	210 g
	Granulated sugar	48 g
	33% sugar-plant-sterol mixture	55 g
15	Salt	5 g
	Cardamom	3 g
	Margarine	100 g
	Milk	250 g
	Baking yeast (compressed)	25 g

20

The dough lay time was 40 min, temperature 36°C and humidity 75%. The dough was moulded into small buns, proofed for 30 min at a temperature of 36°C and in 75% humidity and baked in the oven for 10 min at a temperature of 225°C.

25 Buns containing no plant sterol were prepared according to the same recipe as a reference sample. The appearance of buns containing plant sterol completely corresponded to that of the reference sample. Likewise, aroma, taste and structure (porosity, pore size, smoothness) were identical. It was clearly found also here that the plant sterol gives a bakery product an agreeable fatty feel that remains longer than in a conventional bun.

30

#### **Example 11**

##### **Preparation of buns containing plant sterol**

Buns were prepared according to the following recipe. The plant sterol was added by replacing part of the wheat flour with flour-plant-sterol mixtures that were prepared according to examples 2 or 3. The plant sterol

35

mixtures must be added well mixed to the wheat flour. The plant sterol content of the dough was 2%.

Composition of buns was as follows:

5	Wheat flour, semi-coarse	32 g
	Wheat flour, coarse	210 g
	10% wheat-flour-plant-sterol mixture	178 g
	Sugar	85 g
	Salt	5 g
10	Cardamom	3 g
	Margarine	100 g
	Milk	250 g
	Baking yeast	25 g

15 The dough lay time was 40 min, temperature 36°C and humidity 75%. The dough was moulded into small buns, proofed for 30 min at a temperature of 36°C and in 75% humidity, and baked in the oven for 10 min at a temperature of 225°C.

20 Buns containing no plant sterol were prepared according to the same recipe as a reference sample. The appearance of the buns containing plant sterol completely corresponded to that of the reference sample. Likewise, aroma, taste and structure (porosity, pore size, smoothness) were identical. The bun containing plant sterol had a moister mouth-feel and it kept its freshness longer.

#### 25 Example 12

##### Preparation of a rye crispbread containing plant sterol

A crispbread was prepared by using a conventional crispbread recipe (Pieni Pyöreä, Vaasan Mylly). The plant sterol was added by replacing part of the flour with a plant-sterol-flour premix prepared according to example 2 or 30 3, otherwise baking was carried out in a conventional manner. The plant sterol content of the dough was 0.75%.

The characteristics and sensory evaluation of the crispbread containing plant sterol and the reference bread not containing plant sterol are presented in Table 1.

Table 1

Characteristics of rye crispbreads containing 0.75% sitostanol

	Reference	Crispbread containing sitostanol
5		
	I Physical characteristics	
	Height (10 pcs)	86 mm      75 mm
	Weight (10 pcs)	118 g      126 g
	Moisture	6.9%      7.4%
10	Volume weight	0.220 g/ml      0.292 g/ml
	Crumbliness	21      57
	II Sensory evaluation (scale from 1 to 5)	
	Appearance	4      3
15	Smell	5      5
	Taste	4      4
	Structure	4      3

Thus the addition of a plant sterol to a rye crispbread dough has an effect on structure; the bread is flatter than the reference bread, even though it is quite satisfactory as a product. Due to the delicacy of the rye crispbread, it is advisable to keep the amount of plant sterol low, most preferably lower than 1.5%.

### Example 13

#### Preparation of a rye crispbread containing plant sterol

A crispbread was prepared with the method described in example 12, but using a sitostanol-flour premix prepared according to example 3. Alternatively, a pulverized plant sterol having a particle size of less than 132  $\mu\text{m}$ , mixed with the flour before baking, can be used herein.

The rye crispbread corresponded to the product described in example 12.

### Example 14

#### Preparation of a wheat crispbread containing plant sterol

A crispbread was prepared by using a conventional wheat crispbread recipe (Vaasan Mylly). The plant sterol was added by replacing part of the flour with a plant-sterol-flour premix that was prepared according to exam-

ples 2 or 3. The plant sterol content of the dough was 1.5%. Moreover, a crispbread not containing plant sterol was prepared as a reference sample. The characteristics and the results of sensory evaluation of the breads are presented in Table 2.

5

**Table 2**

Characteristics of wheat crispbreads containing 1.5% sitostanol

	Reference	Crispbread containing sitostanol
<b>I Physical characteristics</b>		
10 Height (10 pcs)	84 mm	73 mm
Weight (10 pcs)	143 g	146 g
Moisture	7.0%	8.0%
Volume weight	0.255 g/ml	0.305 g /ml
Crumbliness	20	29
<b>II Sensory evaluation (scale from 1 to 5)</b>		
15 Appearance	4	4
Smell	5	5
Taste	5	4
20 Structure	4	3

Compared with reference breads, the breads containing sitostanol were slightly harder and more solid, and good in the appearance, aroma, taste and mouth-feel.

25

**Example 15****Preparation of a wheat crispbread containing plant sterol**

A crispbread was also prepared to which the plant sterol was added as a plant-sterol-sugar mixture prepared according to example 4. The amount of sitostanol in the dough was 1.5%. This test also produced a bread that was slightly harder and more solid and whose characteristics corresponded to those of the bread described in the previous example.

30

**Example 16****Preparation of a crispbread of the digestive type containing plant sterol**

35

A crispbread was prepared by using a conventional digestive crispbread recipe (Vaasan Mylly). The plant sterol was added by replacing part of

the wheat flour with a plant-sterol-flour premix prepared according to examples 2 or 3. The plant sterol content of the dough was 1.5%. Moreover, a crispbread not containing plant sterol was prepared as a reference bread. Baking results are presented in Table 3

5

**Table 3**

Characteristics of digestive crispbreads containing 1.5% sitostanol

	Reference	Crispbread containing sitostanol
I Physical characteristics		
10 Height (10 pcs)	67 mm	61 mm
Weight (10 pcs)	194.4 g	184.0 g
Moisture	5.5%	5.4%
Volume weight	0.371 g/ml	0.381 g/ml
Crumbiness	27	29
15 II Sensory evaluation (scale from 1 to 5)		
Appearance	4	5
Smell	5	5
Taste	5	5
20 Structure	3	3

Compared with the reference bread, the breads containing sitostanol had a slightly harder and more solid structure, and their appearance, aroma, taste and mouth-feel were very good.

25

**Example 17**

**Preparation of a crispbread of the digestive type containing plant sterol**

A digestive crispbread was also prepared to which the plant sterol was added as a plant-sterol-sugar mixture prepared according to example 4.

30

The amount of sitostanol in the dough was 1.5%. Also this test provided an excellent product whose characteristics corresponded to those of the bread described in the previous example.

**Example 18**

**Preparation of oat biscuits containing plant sterol**

## 20

Plant sterol was added to a dough by replacing part of the wheat flour with a plant-sterol-wheat-flour mixture prepared according to example 3. The plant sterol content of the dough was 1.5%.

## Biscuit composition:

5	Oat flakes	3/4 dl
	Wheat flour	60 g
	10% plant sterol-wheat flour mixture	60 g
	Raisins	1/2 dl
	Sugar	1 dl
10	Margarine	100 g
	Baking powder	1/2 tsp
	Milk	3/4 dl

The flour, plant-sterol-wheat-flour mixture and baking powder were mixed together. To melted margarine were added sugar, raisins, oat flakes, flour mixture and lastly milk. The dough was allowed to rest for half an hour at a cool temperature (4°C). The biscuit dough was rolled into small balls that were baked in the oven for 10 min at a temperature of 200°C.

Biscuits not containing plant sterol were prepared according to the same recipe as a reference sample. The biscuits containing plant sterol were slightly more compact, but otherwise their taste and structure corresponded to those of the reference sample.

**Example 19****Preparation of oat biscuits containing plant sterol**

Plant sterol was added to a dough by replacing part of the sugar with a plant-sterol-sugar mixture prepared according to example 4. The plant sterol content of the dough was 1.5%.

## Biscuit composition:

	Oat flakes	3/4 dl
30	Wheat flour	120 g
	Raisins	1/2 dl
	Sugar	73 g
	33% plant-sterol-sugar mixture	18 g
	Margarine	100 g
35	Baking powder	1/2 tsp
	Milk	1/4 dl

The plant-sterol-sugar mixture and wheat flour were mixed together. To melted margarine were added sugar, raisins, oat flakes, flour-plant-sterol-sugar mixture into which the baking powder was mixed, and lastly milk. The dough was allowed to rest for half an hour at a cool temperature (4°C). The  
 5 biscuit dough was rolled into small balls that were baked in the oven for 10 min at a temperature of 175°C.

Biscuits not containing plant sterol were prepared according to the same recipe as a reference sample. The biscuits containing plant sterol were slightly more solid, but otherwise their taste and structure corresponded to  
 10 those of the reference sample.

#### **Example 20**

##### **Preparation of a shortcake containing plant sterol**

Plant sterol was added to a batter by replacing part of the wheat flour with a plant-sterol-wheat-flour premix prepared according to example 3.  
 15 The plant sterol content of the batter was 1.5%.

##### **Shortcake composition:**

	Wheat flour	80 g
	10% plant-sterol-flour mixture	114 g
	Sugar	2 dl
20	Vanilla sugar	2 tsp
	3 eggs	
	Margarine	200 g
	Baking powder	2 tsp

25 Margarine and sugar were creamed by beating, and the eggs were added to the mixture. The flour and plant-sterol-flour mixture was added to the cream. The batter was poured into a cake tin and baked in the oven for 50 min at a temperature of 175°C.

A cake not containing plant sterol was prepared as a reference  
 30 sample. The cake containing plant sterol was slightly lower and moister inside, otherwise it corresponded to the reference sample.

#### **Example 21**

##### **Preparation of a shortcake containing plant sterol**

Plant sterol was added to a batter by replacing part of the sugar  
 35 with a plant-sterol-sugar mixture prepared according to example 4. The plant sterol content of the batter was 2%.

## 22

## Shortcake composition:

	Wheat flour	3 dl
	Sugar	146 g
	33% plant-sterol-sugar mixture	34 g
5	Vanilla sugar	2 tsp
	3 eggs	
	Margarine	200 g
	Baking powder	2 tsp

- 10           Margarine, sugar and plant-sterol-sugar mixture were creamed by beating and the eggs were added to the mixture. The flour was mixed into the froth. The batter was poured into a cake tin and baked in the oven for 50 min at a temperature of 175°C.

- 15           A cake not containing plant sterol was prepared as a reference sample. The cake containing plant sterol was slightly lower and moister inside, but otherwise it corresponded to the reference sample.

**Example 22****Preparation of a thin rye crispbread containing plant sterol**

- 20           Thin crispbreads were prepared by using a conventional thin crispbread recipe (Vaasan Mylly). Plant sterol was added by replacing part of the flour with a plant-sterol-flour mixture prepared according to examples 2 or 3. The plant sterol content of the dough was 1.5%. Moreover, thin crispbreads not containing plant sterol were prepared as a reference sample. The baking results are presented in Table 4.

25

**Table 4**

Characteristics of thin crispbreads containing 1.5% sitostanol

	Reference	Thin crispbread containing sitostanol
I Physical characteristics		
30           Height (10 pcs)	40 mm	43 mm
	Moisture	3.7%
	Volume weight	0.278 g/ml
	pH	4.57
	Acid value	18.5



## 23

## II Sensory evaluation (scale from 1 to 5)

	Appearance	4	4
	Smell	5	5
	Taste	4	4
5	Structure	4	4

Compared with the reference bread, the thin crispbreads containing sitostanol were similar, and by appearance, aroma, taste and mouth-feel they were very good.

10 **Example 23****Preparation of a sausage containing plant sterol**

A sausage was prepared by using a conventional cooked sausage recipe with following ingredients:

	Beef-based ingredients	30 - 40 %
15	Pork-based ingredients	30 %
	Water	25 %
	Milk powder and/or potato flour, wheat flour	5 %
	Salt	1.5 %
20	Admixtures (phosphates, etc)	1 - 2 %

Plant sterol was added by replacing milk powder with a mixture of milk powder and plant sterol in which the proportion of plant sterol was 20 % and which was prepared in the manner described in example 3.

25 A product of a Finnish ring sausage type was produced of the mixture, the product corresponding in structure and taste to a reference sausage not containing plant sterol.

A sausage of a meetwurst type can be prepared in a corresponding manner, in which the plant sterol can be ground either with admixtures or  
30 meat.

**Example 24****Preparation of an animal feed containing plant sterol**

A chicken feed was prepared by using the following basic recipe of chicken feed:

35	Starch raw material (mainly barley)	60 - 70 %
----	--	-----------

- |   |                                      |           |
|---|--------------------------------------|-----------|
|   | Protein component                    | 20 - 30 % |
|   | (mainly crushed soybean)             |           |
|   | Other ingredients                    | 5 - 10 %  |
| 5 | - minerals (mainly $\text{CaCO}_3$ ) |           |
|   | - vitamins                           |           |
|   | - trace elements                     |           |
|   | - amino acids                        |           |
|   | - enzymes, if any                    |           |
- 10           The plant sterol was ground with  $\text{CaCO}_3$  in the manner described in example 3 into a premix containing about 20% of plant sterol. Thus the final plant sterol content of the feed mixture was 1%. A high cholesterol level is necessary for growing chickens. For this reason, the mixture containing plant sterol is recommended for hens in egg production.
- 15           A corresponding animal feed, for instance pig feed, with a cereal ingredient content of 60 to 80 %, can also be prepared by grinding a plant sterol and a cereal ingredient into a premix in the above-described manner.

## CLAIMS

1. A premix, **characterized** by containing a pulverized plant sterol and a conventional foodstuff raw material that is selected from a group comprising cereal, leguminous plants, milk powder, fruits, vegetables and/or  
5 berries, fish, meat, bone, feather or rind.
2. A premix as claimed in claim 1, **characterized** in that the plant sterol is sitosterol, sitostanol, campestenol, clionastanol, brassicasterol or a mixture thereof.
3. A premix as claimed in claim 2, **characterized** in that the  
10 plant sterol is  $\beta$ -sitosterol or  $\beta$ -sitostanol, preferably  $\beta$ -sitostanol.
4. A premix as claimed in any one of claims 1 to 3, **characterized** in that the raw material is wheat, rye, oat, barley, buckwheat, millet, rice, maize, soybean, bean or potato starch.
5. A premix as claimed in any one of claims 1 to 4, **characterized**  
15 **terized** in that the amount of plant sterol is about 1 to 60 % by weight, preferably about 5 to 50 % by weight, more preferably 10 to 40 % by weight and most preferably 10 to 20 % by weight.
6. A premix as claimed in any one of claims 1 to 5, **characterized**  
20 **terized** by containing 5 to 25 % sitosterol or sitostanol, preferably about 10 to 20 %, and cereal.
7. A premix as claimed in claim 6, **characterized** in that the cereal is wheat, rye, buckwheat or maize flour.
8. A premix as claimed in any one of claims 1 to 7, **characterized**  
25 **terized** in that the mean particle size of the pulverized premix is less than about 600  $\mu\text{m}$ , preferably less than 132  $\mu\text{m}$ , more preferably 60 to 70  $\mu\text{m}$ .
9. A method for the manufacture of a premix, **characterized** in that a plant sterol and a conventional foodstuff raw material which is cereal, leguminous plant, milk powder, berry, vegetable or fruit, fish, meat, bone, feather or rind are ground into a pulverized and homogenous mixture.
- 30 10. A method as claimed in claim 9, **characterized** in that the plant sterol and the cereal are impact-milled together.
11. A method as claimed in claim 10, **characterized** in that the ingredients are impact-milled together to a mean particle size of less than about 600  $\mu\text{m}$ , preferably about 500  $\mu\text{m}$ .

12. A method as claimed in claim 9 or 10, **characterized** in that the cereal is in a form of whole grains, husked grains and/or pre-crushed grains.

13. A method as claimed in claim 9, **characterized** in that  
5 the ingredients are ground with an air jet grinder.

14. A method as claimed in claim 13, **characterized** in that the plant sterol and the cereal are jet-pulverized together to a mean particle size of less than 200  $\mu\text{m}$ , preferably less than 20 to 132  $\mu\text{m}$ , most preferably about 20 to 70  $\mu\text{m}$  and particularly 60 to 70  $\mu\text{m}$ .

10 15. A method as claimed in claim 9, **characterized** in that the pulverized ingredients with a particle size of less than about 132  $\mu\text{m}$  are formed separately and thereafter combined into a homogenous mixture.

16. Use of a premix as claimed in any one of claims 1 to 8 as a cholesterol-lowering substance edible as such.

15 17. Use of a premix as claimed in any one of claims 1 to 8 in the manufacture of edible substances.

18. Use as claimed in claim 17, **characterized** in that the premix is used in food processing industry, meat processing industry, dairy industry, baking industry, confectionery industry, beverage industry or animal  
20 feed industry.

19. Use as claimed in claim 18, **characterized** in that the premix is used for manufacturing bakery products.

20. A bakery product, **characterized** by containing a premix as claimed in any one of claims 1 to 8 and conventional ingredients of bakery  
25 products.

21. A bakery product as claimed in claim 20, **characterized** by being a plain bread, a sweet bakery product, a crispbread, a sweet or salted biscuit, a rusk, a thin crispbread, a cracker, a baked snack or a wafer.

22. A bakery product as claimed in claim 20 or 21, **characterized**  
30 **terized** by containing about 0.3 to 5.0 %, preferably about 0.5 to 3.0 % and most preferably about 1 to 2 % of plant sterol.

23. Use of a premix as claimed in any one of claims 1 to 8 as a cholesterol-lowering substance.

24. Use of an edible product containing a premix as claimed in any  
35 one of claims 1 to 8 as a cholesterol-lowering substance.

25. Use of a plant sterol in bakery products as an anti-staling agent.

26. Bakery products, characterized by containing plant sterol as an anti-staling agent.

## AMENDED CLAIMS

[received by the International Bureau on 10 November 1998 (10.11.98);  
original claims 1-26 replaced by new claims 1-27 (3 pages)]

1. A premix, characterized by containing a pulverized plant sterol and/or stanol and a conventional foodstuff raw material that is selected from a group comprising cereal, leguminous plants, milk powder, fruits, vegetables and/or berries, fish, meat, bone, feather or rind, and having a mean particle size of less than about 600  $\mu\text{m}$ .
2. A premix as claimed in claim 1, characterized in that the particle size of the pulverized plant sterol or stanol in the mixture is less than 200  $\mu\text{m}$ , preferably less than 132  $\mu\text{m}$ .
- 10 3. A premix as claimed in claim 1 or 2, characterized in that the plant sterol or stanol is sitosterol, sitostanol, campestenol, clionastanol, brassicasterol or a mixture thereof.
4. A premix as claimed in claim 3, characterized in that the plant sterol or stanol is  $\beta$ -sitosterol or  $\beta$ -sitostanol, preferably  $\beta$ -sitostanol.
- 15 5. A premix as claimed in any one of claims 1 to 4, characterized in that the raw material is wheat, rye, oat, barley, buckwheat, millet, rice, maize, soybean, bean or potato starch.
6. A premix as claimed in any one of claims 1 to 5, characterized in that the amount of plant sterol or stanol is about 1 to 20 60 % by weight, preferably about 5 to 50 % by weight, more preferably 10 to 40 % by weight and most preferably 10 to 20 % by weight.
7. A premix as claimed in any one of claims 1 to 6, characterized by containing 5 to 25 % sitosterol or sitostanol, preferably about 10 to 20 %, and cereal.
- 25 8. A premix as claimed in claim 7, characterized in that the cereal is wheat, rye, buckwheat or maize flour.
9. A premix as claimed in any one of claims 1 to 8, characterized in that the mean particle size of the pulverized premix preferably is less than 132  $\mu\text{m}$ , more preferably 60 to 70  $\mu\text{m}$ .
- 30 10. A method for the manufacture of a premix, characterized in that a plant sterol and/or stanol and a conventional foodstuff raw material which is cereal, leguminous plant, milk powder, berry, vegetable or fruit, fish, meat, bone, feather or rind are ground into a pulverized and homogenous mixture having a mean particle size of less than about 600 35  $\mu\text{m}$ .

11. A method as claimed in claim 10, **characterized** in that the plant sterol and/or stanol and the cereal are impact-milled together.

12. A method as claimed in claim 11, **characterized** in that the ingredients are impact-milled together to a mean particle size of less than  
5 about 600  $\mu\text{m}$ , preferably about 500  $\mu\text{m}$ .

13. A method as claimed in claim 10 or 11, **characterized** in that the cereal is in a form of whole grains, husked grains and/or pre-crushed grains.

14. A method as claimed in claim 10, **characterized** in that  
10 the ingredients are ground with an air jet grinder.

15. A method as claimed in claim 14, **characterized** in that the plant sterol and/or stanol and the cereal are jet-pulverized together to a mean particle size of less than 200  $\mu\text{m}$ , preferably less than 20 to 132  $\mu\text{m}$ , most preferably about 20 to 70  $\mu\text{m}$  and particularly 60 to 70  $\mu\text{m}$ .

16. A method as claimed in claim 10, **characterized** in that  
15 the pulverized ingredients with a particle size of less than about 132  $\mu\text{m}$  are formed separately and thereafter combined into a homogenous mixture.

17. Use of a premix as claimed in any one of claims 1 to 9 as a cholesterol-lowering substance edible as such.

20 18. Use of a premix as claimed in any one of claims 1 to 9 in the manufacture of edible substances.

19. Use as claimed in claim 18, **characterized** in that the premix is used in food processing industry, meat processing industry, dairy industry, baking industry, confectionery industry, beverage industry or animal  
25 feed industry.

20. Use as claimed in claim 19, **characterized** in that the premix is used for manufacturing bakery products.

21. A bakery product, **characterized** by containing a premix as claimed in any one of claims 1 to 9 and conventional ingredients of bakery  
30 products.

22. A bakery product as claimed in claim 21, **characterized** by being a plain bread, a sweet bakery product, a crispbread, a sweet or salted biscuit, a rusk, a thin crispbread, a cracker, a baked snack or a wafer.

23. A bakery product as claimed in claim 21 or 22,  
35 **characterized** by containing about 0.3 to 5.0 %, preferably about 0.5 to 3.0 % and most preferably about 1 to 2 % of plant sterol and/or stanol.

24. Use of a premix as claimed in any one of claims 1 to 9 as a cholesterol-lowering substance.

25. Use of an edible product containing a premix as claimed in any one of claims 1 to 9 as a cholesterol-lowering substance.

5        26. Use of a plant sterol and/or stanol in bakery products as an anti-staling agent.

27. Bakery products, characterized by containing plant sterol and/or stanol as an anti-staling agent.



**STATEMENT UNDER ARTICLE 19**

Replacement sheets 25-27 shall replace original pages 25-27, whereby amended claims 1-27 replace original claims 1-26.

In the claims, the following amendments have been made:

Original claim 1 has been amended by introducing "and having a mean particle size of less than about 600  $\mu\text{m}$ " on the basis of original claim 8. Further, the wording "plant sterol" has been replaced with "plant sterol and/or stanol" in original claim 1, as well as in original claims 9, 10, 14, 22, 25 and 26, and with "plant sterol or stanol" in original claims 2, 3, and 5. These amendments are based on the description of suitable plant sterols given in the application, e.g. page 4, lines 15-21, English text, the examples and original claim 6.

A new claim 2, defining a preferred particle size of 200  $\mu\text{m}$ , preferably less than 132  $\mu\text{m}$ , on the basis of page 8, lines 26-30, has been introduced. As a result, original claims 2-26 have been renumbered as claims 3-27 and possible referrals to other claims have been amended accordingly.

Original claim 8 has been amended by deleting the wording "is less than about 600  $\mu\text{m}$ ", as this has been added to claim 1.

Original method claim 9 has further been amended in a corresponding manner as original product claim 1 by introducing "having a mean particle size of less than about 600  $\mu\text{m}$ " on the basis of original claim 8.

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## ATREX LABORATORY EQUIPMENT (GRINDER VERSION)

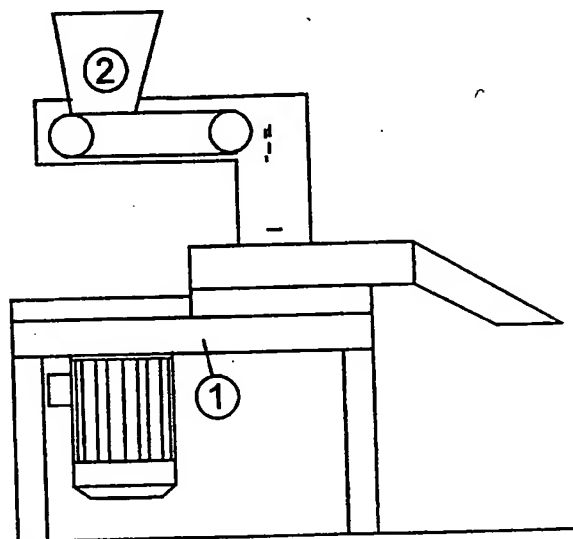
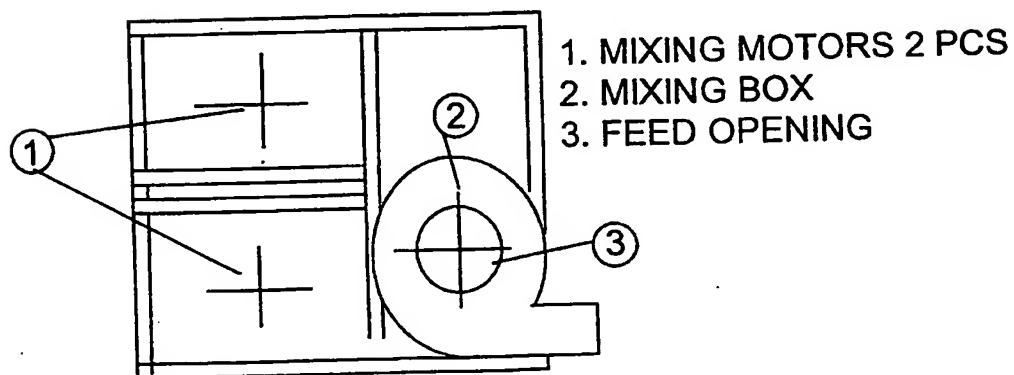
TOP VIEW OF ATREX  
(WITHOUT DOSING FEEDERS)

FIG. 1

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## SCHEMATIC VIEW OF ATREX ROTORS

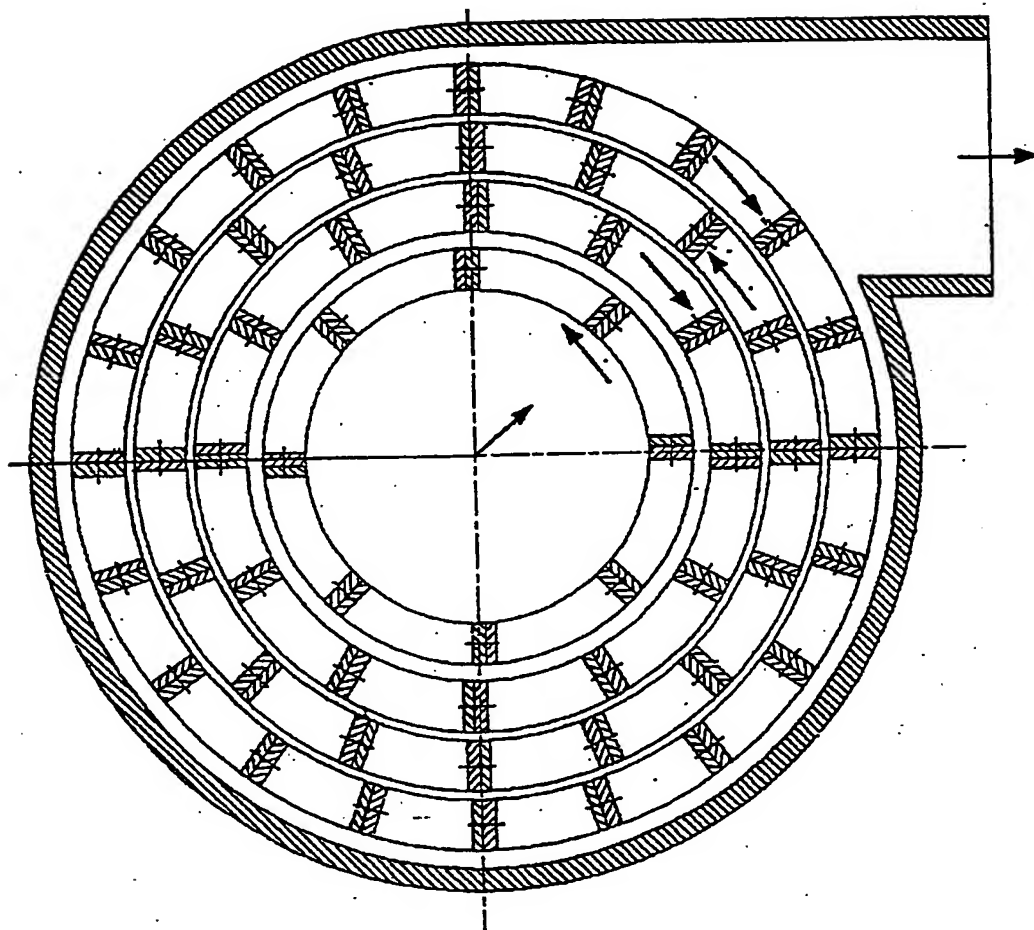
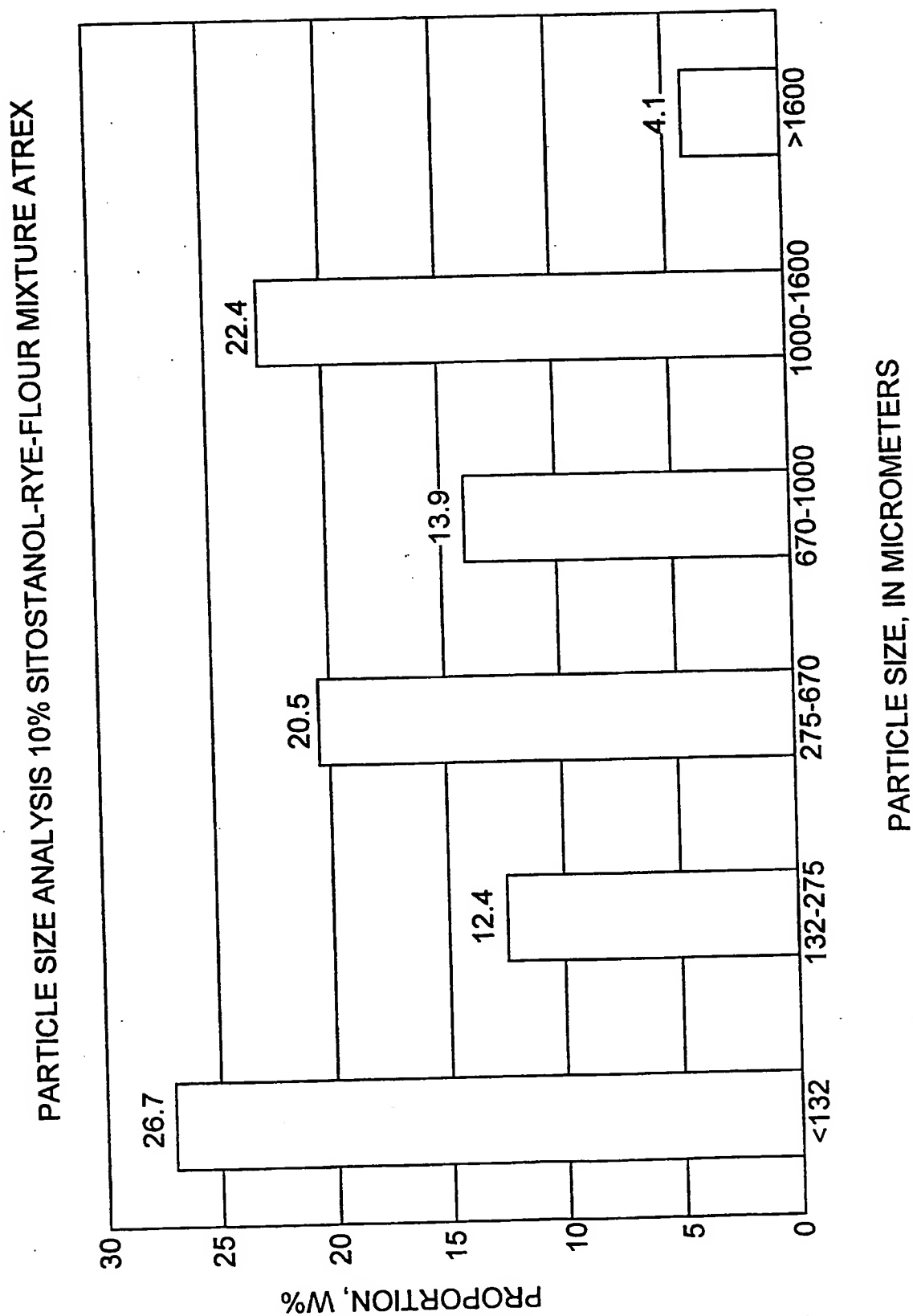


FIG. 2



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PAMAS  
PARTICLE MEASURING AND ANALYSIS SYSTEM

CULTOR

VERSION 3.05 S#: B300039

OPERATOR: AJN

DATE: 21.04.1997 TIME: 11:36:50

SAMPLE: SITOSTANOL: 3. GROUND ONCE ATREX 11.4-97

SENSOR: HCB-50/25 2.00-190.00 LOG. 1-16

POP %, POP %&lt;, VOL %, VOL%&lt;

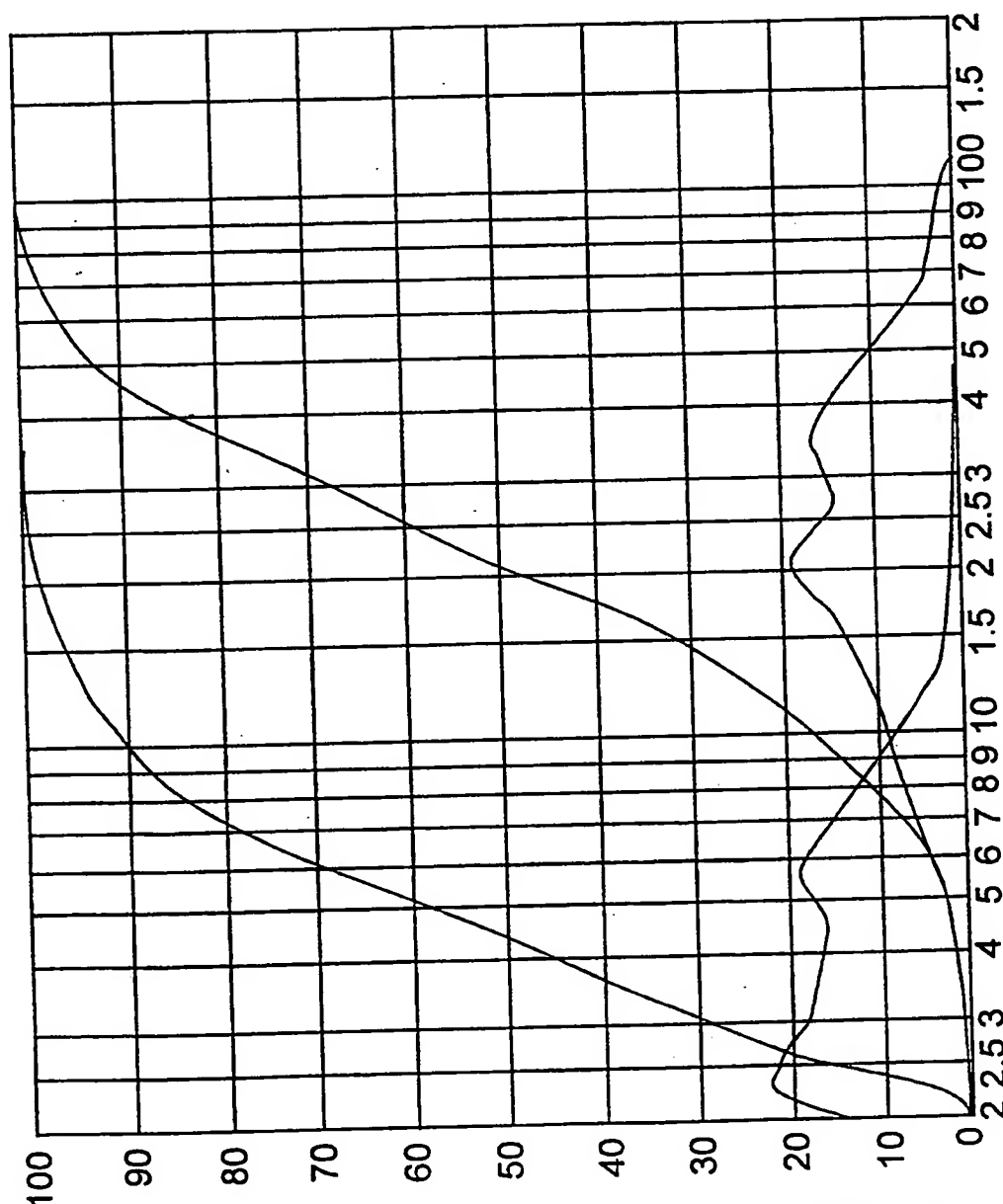


FIG. 4

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/FI 98/00503

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A23L 1/29, A21D 2/08, A21D 13/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A23L, A21D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CA, WPI, EPODOC

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 934686 A (C.F. BOEHRINGER & SOEHNE G.M.B.H.), 21 August 1963 (21.08.63) --	1-26
Y	US 3881005 A (ARVIND L. THAKKAR ET AL), 29 April 1975 (29.04.75) --	1-26
Y	US 5244887 A (CARL D. STRAUB), 14 Sept 1993 (14.09.93) --	1-26
Y	WO 9508342 A1 (INPHARMA S.A.), 30 March 1995 (30.03.95) --	1-26

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

25 Sept 1998

Date of mailing of the international search report

25-09-1998

Name and mailing address of the ISA/

Swedish Patent Office

Box 5055, S-102 42 STOCKHOLM

Facsimile No. +46 8 666 02 86

Authorized officer

Eva Johansson

Telephone No. +46 8 782 25 00

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/FI 98/00503

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	File WPI, Derwent accession no. 75-18814W, Leningrad Food Res Inst: "Dietetic pastries contg. beta-sitosterol - for use by patients with lipid exchange disorder;" & SU,A,414989, 740918, DW7511  --	1-26
Y	File WPI, Derwent accession no. 91-027533, Snow Brand Milk Prod Co Ltd: "Mfg. biscuits for improving lipid in blood - by admixing vegetable sterol contg. beta-sitosterol in flour;" & JP,A,2299548, 901211, DW9830  --	1-26
A	Food Chemistry, Volume 8, 1982, I.B. Agater et al, "Determination of Beta-Sitosterol in Meats, Soya and other Protein Products" page 43 - page 49  --	1-26
A	File WPI, Derwent accession no. 87-268028, Ajinomoto KK et al: "Stabilised sterol compsn. - comprises emulsion or soln. of sterol in liq. poly: ol or its aq. soln. with sucrose- and/or poly:glycerol-fatty acid ester(s);" & JP,A,62186936, 870815, DW8738  --	1-26
P,X	WO 9813023 A1 (SUOMEN SOKERI OY), 2 April 1998 (02.04.98)	1-18,23-24
P,A	  -- -----	19-22,25-26

## INTERNATIONAL SEARCH REPORT

Information on patent family members

27/07/98

International application No.

PCT/FI 98/00503

Patent document cited in search report			Publication date	Patent family member(s)	Publication date
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				DE 1131845 B	00/00/00
				DE 1139236 B	00/00/00
				LU 41386 A	15/05/62
				NL 142069 B	15/05/74
				NL 276700 A	00/00/00
US	3881005	A	29/04/75	AR 202034 A	09/05/75
				AT 655474 A	15/02/77
				AU 7155674 A	29/01/76
				BE 818729 A	12/02/75
				DD 112899 A	12/05/75
				DE 2437845 A	27/02/75
				DK 427674 A	21/04/75
				FR 2240717 A,B	14/03/75
				JP 50048115 A	30/04/75
				NL 7410862 A	17/02/75
				SE 7410331 A	14/02/75
				ZA 7404587 A	25/02/76
US	5244887	A	14/09/93	NONE	
WO	9508342	A1	30/03/95	CH 685283 A	31/05/95
				EP 0669835 A	06/09/95
				JP 8503964 T	30/04/96
WO	9813023	A1	02/04/98	AU 4461497 A	17/04/98
				FI 963904 A	28/03/98



# INTERNATIONAL SEARCH REPORT

International application No.

PCT/FI 98/00503

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 16,23,24 partly  
because they relate to subject matter not required to be searched by this Authority, namely:  
See PCT Rule 39.1(iv): Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.